Appendix 1: 510(k) Summary per 21CFR §807.92

Submitter's information

Topera, Inc.
3668 S. Geyer Road, Suite 365
St. Louis, MO 63127
Contact: Dennis Pozzo
Phone 314-300-6580
Date: Oct. 24, 2013

DEC 16 2013

Device/ classification name

- Device Name: RhythmView™ Workstation
- Classification/Common name: Programmable diagnostic computer
- The marketed device(s) to which substantial equivalence is claimed:
  - K123295, cleared April 24, 2013
  - K110878, cleared Sept. 23, 2011

Device description

The RhythmView™ Workstation is comprised of the following components:

Cart	Keyboard
Monitor/Display	Mouse
Computer	Software

RhythmView™ takes electrical signals collected from multi-polar electrophysiology catheters and outputs a graphic display that assists in the diagnosis of cardiac arrhythmias.

The RhythmView™ computes and displays electrical rotors or focal beat sources responsible for maintaining human heart rhythm disorders including focal AT, AFL, other SVT, AF, VT and VF in a given patient. The product takes as input electrical signals recorded during the heart rhythm disorder under consideration, typically from multiple specified locations within the heart during an electrophysiological study. The RhythmView™ then uses proprietary patented algorithms and methods to compute spatial organization during the heart rhythm disorder. These computed elements are displayed graphically in interactive form for review to aid diagnosis by the physician during an electrophysiology study.

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Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

Indications for use

The RhythmView™ Workstation is a computerized system that assists in the diagnosis of complex cardiac arrhythmias. The RhythmView™ Workstation is used to analyze electrogram and electrocardiogram signals and display them in a visual format.

Technological characteristics

Both the proposed and predicate RhythmView™ Workstations allows the user to:

- Review and select a time sequence of electrical signals from various electrodes;
- Analyze the signals;
- View a graphic display (Electrical Activity) of the signal potentials showing progressive depolarization and repolarization in grayscale for the particular arrhythmia;
- Play (or replay) this animated graphic representation of electrical signals.

The new RhythmView™ provides an additional display option, "Rotational Activity Profile" display as an overlay on the UI.

Both are software driven devices that translate electrical signals within the heart into graphic representations in order to assist the physician in diagnosis.

Device Characteristic	Predicate Device RhythmView™ 4.0	Proposed Device RhythmView™ 4.1
Signal processing	Yes	Yes
Post-processing display	Yes	Yes
Grid display of electrode signals	Yes	Yes
Programming Language	C++	C++
Export of processed file into video format	Yes	Yes
Manual tagging by user of electrograms	No	No
OTS Software requirements	Same	Same

Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

Technological characteristics continued

Display options for review of processed signals	• Electrical Activity • Contours Only • DContours • P+RContours • P+Contours • P+DContours	• Electrical Activity • Contours Only • DContours • Rotational Activity Profile"

Performance data

Based upon the software testing that has been performed, which provide reasonable assurance that the proposed device has been tested to verify conformance to requirements for its intended use. Therefore, it has been demonstrated that the RhythmView™ Workstation is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 16, 2013

Topera, Inc.
Mr. Dennis Pozzo
3668 S. Geyer Road Suite 365
St. Louis, MO 63127 US

Re: K133305
Trade/Device Name: Rhythm View Workstation V4.1
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: November 15, 2013
Received: November 18, 2013

Dear Mr. Dennis Pozzo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 , please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 2: Indications for Use Statement

Statement

The Indications for Use Statement:

510(k) Number: K 133305

Device Name: RhythmView™ Workstation

The RhythmView™ Workstation is a computerized system that assists in the diagnosis of complex cardiac arrhythmias. The RhythmView™ Workstation is used to analyze electrogram and electrocardiogram signals and display them in a visual format.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.12.16 16:30:51 -05'00'

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